February 4, 2000

MEMORANDUM

SUBJECT: RESPONSE TO FQPA COMMITTEE REQUEST REGARDING SAP COMMENTS FOR DDVP RESIN STRIPS (PC Code 084001, Case No. 819293, Barcode D251331)

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In July 1998 the Agency presented exposure assessments for resin strip products containing DDVP to the FIFRA Scientific Advisory Panel (SAP). Four methods for determining respiratory exposure were presented. The SAP recommended that a time weighted average approach be used to address this exposure scenario.
This approach, after correction of a mathematical error was used for the resin strip assessment in the Reregistration Eligibility Document (RED) for this compound. The results of the chronic and acute exposure risks from that document are presented in Tables 1 and 2. The SAP had additional comments concerning the Agency's risk assessment for these products.

The Panel "expressed concern that the Agency's current exposure assessment for DDVP resin strips (and perhaps for indoor residential exposures in general) fails to address the multi-route nature of residential exposure. The four exposure models consider only exposure by inhalation, and therefore neglect to consider DDVP concentrations in rugs, upholstery, or clothing which may lead to dermal exposure and/or oral exposure (i.e. hand to mouth activities). All of these are known to be sinks for organic molecules, and the behavior of toddlers, ignored in all models, makes these data of critical importance. Children of this age spend large amounts of time crawling over carpets, and putting their hands in their mouths. None of the models include such sources and pathways, and so suffer from a substantial specification error. One Panel member recounted recent research findings which have shown that residues of dichlorvos in soil vacuumed from carpet increased some 70 times over a 5 to 6 month

period (ca. 0.01 ppm, 14 days; 0.7 ppm, 150 days) following an outdoor perimeter application. The formulation used was a combination of chlorpyrifos/dichlorvos. How much of this residue was transferred either to the skin or from hand to mouth contact is unknown, but one can assume that some gets into the body. Data including soil, surface and airborne residues should be included in any exposure model. In summary, the data on which the Agency's current residential exposure assessment for DDVP resin strips is based must be considered incomplete. The registrant should be requested to furnish this information to allow an informed estimate of exposure to be made."

The Agency has no data addressing surface residues that might arise from the use of a resin strip but notes that the concentrations found in the air in the study, which are presented in Table 3, are quite low. Most are less than 100 ng per liter. It is further noted that residues in foodstuffs monitored at the same time as the air measurements yielded almost all non-detect levels of the chemical, indicating that little or no chemical was adsorbed on these items. At these low concentrations the Agency concluded that, while possible, the relative contribution of any vapor molecules that do contact a surface would likely be much smaller than the contribution to total exposure via the respiratory route for resin strips and would add little to the risk assessment. Surface residues are however addressed in total release fogger and lawn care scenarios.

The Panel noted that "none of the models take into account the factors affecting pesticide movement indoors. The environmental conditions (e.g., temperature, relative humidity) that an individual maintains will vary from house to house. In addition, the way a house is kept (i.e., cleaning frequency), traffic patterns, the presence of children and pets all impact on pesticide movement and concentration. It may prove impossible to collect reliable data on all such factors affecting residential exposures, but Agency assessments should address these concerns and consider the uncertainty associated with them in any exposure models or calculations. The Panel reiterated its support of the use of the Agency's Standard Operating Procedures (SOPs) for residential exposures. The SOPs were reviewed by the Panel at its September, 1997 meeting."

There are no available data with which to quantify the effects of temperature, humidity, environmental conditions, or movement ain a house relative to a pest strip. It is the assumption that when monitoring is conducted in occupied houses under "real world" conditions these factors are included in the measurement, although they cannot be partitioned out. The data used for the assessment provided to the SAP is supported by additional information provided by the registrant in which over 100 homes were monitored. The residential SOPs supported by the SAP were intended to be a screen to be used when compound/scenario specific data were not available. In this case compound/product specific data were available and used instead of the default values in the residential SOPs.

"An additional issue raised in the discussion of DDVP resin strips related to the relevance of real world exposures for risk management. The central point is whether Agency exposure analyses should be bounded by label requirements, or whether they should incorporate knowledge of real world exposure conditions. The specific issue

involved the appropriate duration of a time-weighted average (TWA) calculation for residential exposure. Agency analyses of the Collines and DeVries data presented to the Panel included a one day (Day 1) dose estimate, a 56 day analysis using the MCCE Model, and a 91 day TWA calculation. The product label recommends replacement of pest strips after 120 days. A public comment during the meeting by the DDVP registrant indicated that the TWA should be calculated for this time interval. Other label instructions which might be construed as boundaries for exposure analysis include no use of resin strips in homes with infants, no use in children's bedrooms, and no use in food preparation or consumption areas. The Panel believes it is reasonable and important to consider whether a consumer who has just purchased a product to rid a residence of insects will necessarily comply with all of these restrictions. If not, then the Agency needs to determine how to ensure protection for residential occupants, particularly for infants and children.

The notion that exposure analyses must be bound by label requirements rather than real world exposures may have originated in studies of occupational pesticide exposure. In the case of restricted use pesticides, for example, sales are restricted to vendors who are aware of their potential hazards, and the compounds can be applied only by individuals who have been certified as applicators (or those who work under the direct supervision of a certified applicator). The ability to read and understand the label is tested, and continuing education and periodic recertification are required. Also, the Agency has the ability to enforce adherence to label requirements and apply meaningful penalties (e.g., loss of certification). The actual practice has its problems, but the point here is that the regulatory system is designed to control use practices.

Residential exposures, however, differ in nearly all respects from the pesticide applicator example: products such as resin strips are sold "over the counter" and are widely available; sales people are unlikely to be knowledgeable about risks; consumers exhibit great variability in literacy, command of the English language, and predispositions to read or follow label instructions. Monitoring of residential uses is not conducted by federal or state agencies, nor apparently by the registrant, and regulatory agencies are extremely reluctant to enforce label requirements in private residences.

The Panel believes that better knowledge of real world use practices would serve to improve residential exposure analyses, and that the lack of knowledge about actual use (and misuse) for such consumer products as resin strips is an important area of uncertainty in residential exposure analysis. The Panel encourages the Agency and registrants to consider collecting such data to improve estimates of residential exposures."

The Agency lacks the resources or perhaps the regulatory power to address misuse of a resin strip product in the residential environment. Examination of the incidence data for this product shows that there are relatively few incidences. This would support the concept that these products are being used according to label instructions. The study used for risk assessment placed no restrictions on either the number of strips used or the placement of those strips. Some of the strips were located in the kitchen, which was legal at the time, and would address the potential misuse that concerned the Panel.

Table 1. Daily DDVP Concentrations, Chronic Exposures and MOEs of Individuals Occupying Homes in Which Resin Strips Are Installed.

Home	Exposure (µg/kg/day)				Chronic MOE's			
ID	Child 1-4	Child 5-11	Adult (F)	Adult (M)	Child 1-4	Child 5-11	Adult (F)	Adult (M)
1W	0.0029	0.0020	0.0009	0.0011	17	26	54	47
2C	0.0099	0.0067	0.0032	0.0037	5	7	16	14
3C	0.0045	0.0031	0.0015	0.0017	11	16	34	29
4N	0.0026	0.0018	0.0008	0.0010	19	28	59	51
5N	0.0037	0.0025	0.0012	0.0014	14	20	42	37
6N	0.0068	0.0046	0.0022	0.0025	7	11	23	20
7W	0.0083	0.0056	0.0027	0.0031	6	9	19	16
8W	0.0032	0.0022	0.0010	0.0012	16	23	48	42
9C	0.0024	0.0017	0.0008	0.0009	20	30	63	55
10C	0.0123	0.0084	0.0040	0.0046	4	6	13	11
11C	0.0046	0.0031	0.0015	0.0017	11	16	34	29
12N	0.0060	0.0041	0.0020	0.0023	8	12	25	22
13W	0.0087	0.0059	0.0028	0.0032	6	8	18	15
14W	0.0070	0.0048	0.0023	0.0026	7	11	22	19
15N	0.0040	0.0027	0.0013	0.0015	13	19	39	34

Input Parameters: BW: Child 1-4 = 15 kg; Child 5-11 = 22 kg; Adult Female = 60 kg; Adult Male = 70 kg
Daily Respiratory Volume: Child 1-4 = 8700 L/day; Child 5-11 = 8700 L/day; Adult Female = 11300 L/day; Adult Male = 15200 L/day

Table 2. DDVP Concentrations On the First Day After Installation, Acute Exposures, and MOEs of Individuals Occupying Homes in Which Resin Strips Are Installed.

Home ID	Acute Doses (µg/kg/day)[1]				Acute MOE's			
	Child 1-4	Child 5-11	Adult (F)	Adult (M)	Child 1-4	Child 5-11	Adult (F)	Adult (M)
1W	0.0077	0.0053	0.0025	0.0029	65	95	199	173
2C	0.0309	0.0211	0.0100	0.0116	16	24	50	43
3C	0.0155	0.0106	0.0050	0.0058	32	47	100	86
4N	0.0077	0.0053	0.0025	0.0029	65	95	199	173
5N	0.0193	0.0132	0.0063	0.0072	26	38	80	69
6N	0.0426	0.0290	0.0138	0.0159	12	17	36	31
7W	0.0426	0.0290	0.0138	0.0159	12	17	36	31
8W	0.0077	0.0053	0.0025	0.0029	65	95	199	173
9C	0.0039	0.0026	0.0013	0.0014	129	190	398	345
10C	0.0271	0.0185	0.0088	0.0101	18	27	57	49
11C	0.0193	0.0132	0.0063	0.0072	26	38	80	69
12N	0.0193	0.0132	0.0063	0.0072	26	38	80	69
13W	0.0271	0.0185	0.0088	0.0101	18	27	57	49
14W	0.0309	0.0211	0.0100	0.0116	16	24	50	43
15N	0.0155	0.0106	0.0050	0.0058	32	47	100	86

[1] Using measured exposures on day 1.

[2] Input Parameters: Body Weight: Child 1-4 = 15 kg; Child 5-11 = 22 kg; Adult Female = 60 kg; Adult Male = 70 kg
Daily Respiratory Volume: Child 1-4 = 8700 L/day; Child 5-11 = 8700 L/day; Adult Female = 11300 L/day; Adult Male = 15200 L/day

Table 3. Air Concentrations of Dichlorvos (DDVP) in Fifteen Homes in Which Pest Strips Were Installed.

Home ID	Air Cond. type	Rate (ft^3/strip)	Air Concentration (µg/L)						Exponential Decay Parameters		Area Under Curve AUC	Daily Conc. (µg/L) (AUC/120)
			1 Day	7 Days	14 Days	28 Days	56 Days	91 Days	value k	value C0		
1W	Window	1270	0.02	0.02	0.020	0.005[1]	0.005	0.005	0.0177	0.0179	0.8892	0.0074
2C	Central	1440	0.08	0.07	0.07	0.05	0.005	0.020	0.0229	0.0749	3.0670	0.0256
3C	Central	1410	0.04	0.03	0.03	0.01	0.01	0.005	0.0223	0.0337	1.4056	0.0117
4N	None	1410	0.02	0.02	0.01	0.005	0.005	0.005	0.0156	0.0148	0.8069	0.0067
5N	None	1730	0.05	0.02	0.02	0.01	0.005	0.005	0.0232	0.0280	1.1328	0.0094
6N	None	720	0.11	0.06	0.02	0.03	0.01	0.005	0.0303	0.0653	2.0981	0.0175
7W	Window	1080	0.11	0.05	0.06	0.02	0.02	0.005	0.0300	0.0790	2.5617	0.0213
8W	Window	2130	0.02	0.02	0.02	0.01	0.005	0.005	0.0183	0.0205	0.9942	0.0083
9C	Central	6790	0.01	0.01	0.02	0.005	0.005	0.005	0.0111	0.0114	0.7583	0.0063
10C	Central	1500	0.07	0.09	0.06	0.04	0.02	0.020	0.0172	0.0751	3.8113	0.0318
11C	Central	2050	0.05	0.04	0.02	0.02	0.005	0.005	0.0267	0.0396	1.4225	0.0119
12N	None	1550	0.05	0.07	0.02	0.03	0.01	0.005	0.0268	0.0523	1.8754	0.0156
13W	Window	1230	0.07	0.08	0.04	0.04	0.02	0.005	0.0289	0.0802	2.6883	0.0224
14W	Window	1500	0.08	0.05	0.04	0.03	0.01	0.005	0.0300	0.0668	2.1645	0.0180
15N	None	1680	0.04	0.02	0.02	0.02	0.005	0.005	0.0225	0.0297	1.2271	0.0102

[1] The level of detection was 0.01 µg/L, a value of 0.005 was used for these samples.